

# **EXHIBIT F**



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cc: Dr. I. Nozad  
RDCF

### **PROLENE RESIN MANUFACTURING SPECIFICATIONS**

The story of Prolene goes back some 35+ years wherein Ed Block was part of a group of people who contacted the Montecatini Company about the possibility of purchasing some polypropylene fiber for the purposes of making sutures. They visited the offices of Montecatini in NYC (42nd street to be more precise) to look over several samples. During that visit they saw some material with a very nice blue color that they thought would make a new and novel suture. Hence was born the copper phthalocyanate (CPC) colorant. They obtained numerous fiber samples and started testing the samples with positive results. It was Montecatini's formulation that was used. We (Ethicon) were purchasing fiber from them. Montecatini, during this time, informed Ethicon that for business reasons were getting out of the fiber business but were building a polypropylene plant in Kenovah West Virginia (The Novamont plant) and would be willing to sell us resin. The Kenovah plant is literally across the river (the Big Sandy River) from Ashland Kentucky wherein is located the Ashland Oil Refinery. Chicopee was at that time getting into the fiber spinning R&D end of the business and they had a plant in Cornelia Georgia. Hence, the Cornelia/Ethicon/Prolene/Aristech connection was born.

Ethicon then commenced to buy polypropylene resin from Montecatini at their W. Va. Plant. That material was made according to their formulation in their plant for sale to us as a commercial product. During the ensuing years there was a Regulatory concern that this is a very important suture material and the plant might not be able to meet FDA guidelines should an inspection occur. Hence, various deals were struck whereby, for a cost, Ethicon personnel could go in to the plant to insure that the resin was made under proper conditions of cleanliness, etc. and to verify that the formulations were as stated on the run sheets. In addition because of the tenuous position that we were in relative to there being only a single supplier the decision had been made to buy multi year supplies to insure we would always have resin. Hence, the current practice of week to two week long campaigns every few years.

During the ensuing years the plant has been sold and bought by various companies. United States Steel Chemicals, Mitsubishi and semi-independent ownership fall within my 23-year history. However, during all this time the mixing and compounding equipment has not changed although the polypropylene reactor has. In fact the particular WP twin-screw compounder that we use still bears the original Montecatini asset tag. So even though the name of the company may have changed we always bought our Prolene resin from the same plant using the same equipment (with the exception of the polymer reactor) and made by the same people (with the exception of those people who have retired and been replaced).

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We are buying a commercial product from a vendor and have done so for many years. That we are in the plant is at the courtesy of Aristech to insure that their resin formulation is made according to the formulation sheet they publish under the conditions shown on their run sheets. All adjustments to the compounder set points and all equipment are run by Aristech personnel. However, for convenience Ethicon personnel may make minor adjustments to the compounding conditions or assist in the loading of the blender but always in the presence of Aristech personnel and with their full consent.

The objective of every polymer resin run has been to duplicate the original formulation as exactly as possible, "warts and all". Hence, virtually no changes have ever been made in the chemistry with the exception of substituting Procol LA-10 for Luberol and using the polypropylene from a continuous reactor versus the original batch reactor. We substituted Procol LA-10 for Luberol solely because Luberol became no longer available. However, prior to consummating the substitution we validated that the Procol was the same material as the Luberol but from a different vendor. Similarly, we verified that the polypropylene from the continuous reactor was the same composition, molecular weight and molecular weight distribution as that from the batch reactor. That is the two substitutions were indistinguishable from the original formulations.

The additive package in use today is the same as was used in the original formulation from years ago (with the two exceptions as noted in the previous paragraph). In addition in 1991 the Santonox levels were reduced slightly (0.05%). Santonox is an antioxidant that protects the resin from thermal oxidation during extrusion. When this minor change was made the suture extrusion processes were fully validated to demonstrate that no adverse effect on the suture properties resulted from this change. The individual components, levels and purposes are as follow:

Calcium Stearate - 0.25-0.35% - A lubricant to help reduce tissue drag and promote tissue passage.

Dilaurelthiodipropionate (DLTDP) - 0.40-0.60% - An antioxidant to improve long-term storage of the resin and the fiber and to reduce the potential oxidative reaction with ultraviolet light.

Santonox R - 0.10-0.30% - An antioxidant to promote stability during compounding and extrusion.

Procol LA-10 - 0.25-0.35% - A lubricant to help reduce tissue drag and promote tissue passage.

CPC Pigment - 0.55% Max. – A colorant to enhance visibility.

During the resin manufacture we insist that the mixing and compounding equipment be thoroughly cleaned prior to running our material. Aristech and Ethicon personnel inspect the equipment before we commence operations. Once we start the compounding campaign the first 500-1,000 pounds that are compounded are discarded as a matter of course. If the molecular weight of the natural (unpigmented material) is acceptable, as measured by melt flow, we then start collecting material. We always run the unpigmented material campaign first followed by the pigmented material. Depending on the size of the campaign as much as 50,000 pounds of natural resin may be compounded before we switch over to pigmented material. At the time of the switch over we generally discard the first 500-1,000 pounds to insure that the equipment has reached steady state.

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Material leaving the compounder is water quenched, pelletized and airveyor conveyed to the lined polyethylene drums. Each drum is individually sampled, as it is being filled and then closed and sealed when it is full. Generally five drums per mix are obtained. Only drums from a given mix are allowed on a given pallet. No material leaves the plant for shipment to Ethicon without the drum being sealed. Upon receipt at Ethicon the drum seals are checked and verified against the master list prepared at the time of the compounding. The drums containing the individual samples are also sealed at the plant and shipped to Ethicon. Those drums (generally two or three depending on the size of the run) are similarly inspected and the seal numbers verified before the material is tested. All samples are thoroughly tested before any material is accepted into inventory. In addition, several representative samples of the resin are trial extruded before material is used for commercial purposes to insure that no untoward events have occurred.

I hope the above is of some help to you. If you need any additional information please let me know.

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